REMARKS/ARGUMENTS

Claims 1-29 are pending in the present application. Claims 1-3 and 20 have been amended. Reconsideration and allowance of the application is requested in view of the foregoing amendments and the following comments.

Claims 1-5, 7-27 and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gantt et al. in view of Sheth et al. or Remington. As discussed in the background of the present application, tablets from the compression blend containing compressible coated potassium chloride microcapsules, microcrystalline cellulose and magnesium stearate as a lubricant failed to rapidly disperse into granules on contact with water. When a disintegrant was incorporated into the tablet composition to promote rapid disintegration in accordance with the teachings of Remington (see Examples 1-3), a tablet weighing about 2 grams exhibited a hardness of less than 5 kP and unacceptable friability. When tablets from the compression blend containing compressible coated potassium chloride microcapsules and microcrystalline cellulose without including magnesium stearate were compressed into tables weighing about 2 grams, the tablets exhibited poor friability (greater than 1% loss, see Examples 4-6 and 9). These tablets also failed to meet the disintegration time specification set forth in the present application. Tablets containing compressible coated potassium chloride microcapsules, microcrystalline cellulose, disintegrant and a surfactant which typically improves wetting and thereby promotes tablet disintegration in accordance with the disclosure of Gantt et al. exhibited poor friability even though they had acceptable hardness, drug release profile and disintegration time.

Applicants have determined that compressible coated potassium chloride microcapsules when combined with colloidal silicon dioxide alone or in combination with a surfactant in addition to a disintegrant and microcrystalline cellulose provided tablets that met the specific end use requirements. Neither Gantt nor Remington teaches or suggests the use of colloidal silicon dioxide to provide acceptable tablet hardness, friability, and improved disintegration while also providing for controlled release of the drug.

According to the Office action, Sheth teaches the equivalence of magnesium stearate and silicon dioxide. However, the examples in the present application clearly indicate that the two components are not equivalent as used in the present tablet formulation. Comparative examples 1 -3 contained magnesium stearate and resulted in unacceptable tablets with respect to friability while the examples in accordance with certain aspects of the present invention contained colloidal silicon dioxide and resulted in

acceptable tablets. Accordingly, applicants submit that the test data presented in the application demonstrates the differences between the present invention and the prior art and illustrates the non-obviousness of the invention. Therefore, applicants respectfully request that the rejection be withdrawn.

Claims 6 and 28 stand rejected as being unpatentable over the above-cited references in combination with Oshlack et al., U.S. Patent No. 5,472,712. Applicants submit that claims 6 and 28 are patentable for the same reasons as set forth above. Therefore, for at least this reason as well, applicants submit that claims 6 and 28 are patentable over the cited references.

Claims 16 and 27 are believed to be separately patentable because the cited references fail to disclose or suggest preparation of a tablet that is substantially free of lubricants. The prior art references specifically teach the use of a widely used lubricant such as magnesium stearate in the preparation of these types of controlled release formulations. Therefore, tablets that are substantially free of lubricants as set forth in claims 16 and 27 of the present applications are non-obvious over the prior art. Therefore, applicants respectfully submit that these claims are patentable for at least these reasons as well.

Therefore, applicants submit that the claims are in condition for allowance and request that the timely notice of allowance be issued in this case. If the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,

John F. Kane, Reg. No. 44,815

THOMPSON HINE LLP
2000 Courthouse Plaza NE
10 West Second Street
Dayton, Ohio 45402-1758
(937) 443-6816

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